UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. CATHY HOLSPOPPLE, Plaintiffs,	:	CIVIL ACTION NO. 1:15-CV-1671 COMPLAINT AND
v.	:	DEMAND FOR JURY TRIAL
KEYSTONE HEARING INSTITUTE,	:	FILED IN CAMERA AND UNDER
Defendant, and	:	SEAL PURSUANT TO
ANTHONY FOWLER, Au.D,	:	31 U.S.C. § 3730(b)(2)
Defendant, and	:	
JACQUELINE PRICE, Au.D,	:	
Defendant, and	:	
SONOVA HOLDING AG,	:	
Defendant, and	:	
PHONAK LLC,	:	
Defendant.	:	

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COMPLAINT

RELATOR CATHY HOLSPOPPLE ("Relator") on her own behalf, by and through her attorney, Rebecca Lyttle, Esquire, and on behalf of the United States of America ("United States") against KEYSTONE HEARING INSTITUTE ("Defendant Keystone"), ANTHONY FOWLER, Au.D ("Defendant Fowler"), JACQUELINE PRICE, Au.D ("Defendant Price"), SONOVA HOLDING AG ("Defendant Sonova"), and PHONAK LLC ("Defendant Phonak"). Based upon her personal knowledge, relevant documents and upon information and belief, as follows:

I. INTRODUCTION

This is a civil action to recover damages, civil penalties, and other relief owed to the United States and Relator arising from false and/or fraudulent records, statements and claims made, used, and caused to be made, used or presented and continues to be made, used or presented by Defendants, Keystone Hearing Institute; Anthony W. Fowler; Jacqueline Price; Sonova Holdings, AG; and Phonak and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C.§ 3729, et seq., as amended (the "False Claims Act" or "FCA"); the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7a & 7b(b) *et seq.*; The Stark Law, 43 U.S.C. § 1395nn; The Anti-Kickback Act of 1986, 41 U.S.C. §§ 51 *et seq.*; Pennsylvania Fraud and Abuse

Control Act, 62 P.S. § 1401 et seq.; Exclusion Statute, 42 U.S.C. § 1320 A-7; Criminal False Claims Act, 18 U.S.C. § 287; and the Civil Monetary Penalties Law, 42 U.S.C. § 1320 A7-A.

Defendants Keystone, Fowler, and Price defrauded the United States through a systemic pattern and practice of improper billing, providing inadequate services, and other violations of Medicare and other Federal Insurance Program ("FIP") Conditions of Participation; including but not limited to several violations of the Anti-Kickback Laws.

Defendants Sonova and Phonak did not directly submit claims for reimbursement of hearing aids to Federal Insurance Programs; however, they knew that their illegal marketing practices towards and/or with Defendant Keystone through Defendants Fowler and Price would cause the submission of thousands of hearing aid claims that were not eligible for program reimbursement.

Defendants Keystone, Fowler, Sonova, Phonak and Price in connection with submitting claims to and then receiving reimbursement from the Federal Health Care programs, including but not limited to, the United States Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), committed fraud against the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ccc and 42 C.F.R. Parts 400-1004, (a) knowingly

presenting, and causing to be presented to an officer and employee of the United States Government false and fraudulent claims for payment and approved by the Government, in violation of 31 U.S.C. §§ 3729(a)(1) and (2); and (b) knowingly making, using, and causing to be made and used, false records and statements to get false and fraudulent claims paid and approved by the Government, in violation of 31 U.S.C. §§ 3729(a)(1) and (2).

As used in this Complaint, the term Federal Insurance Programs ("FIP") shall have the same meaning as defined in 42 U.S.C. § 1320a-7b(f), and it therefore includes, but not limited to, Medicare, Medicaid, TRI~CARE (administered by the Department of Defense through its component agency, Champus), CHAMPUS'VA (administered by the Department of Veterans Affairs), the Federal Employee Health Benefits Program (administered by the United States Office of Personnel Management), the Railroad Retirement Medicare program (administered by the Railroad Retirement Board), The Federal Workers Compensation Program and the Indian Health Service (administered by the Department of Health and Human Services).

Relator alleges that Defendants committed fraud against some or all of the above Federal Insurances. Defendants have the supporting documentation.

II. PARTIES

Plaintiff / Relator CATHY HOLSOPPLE ("Relator") is an adult individual residing in York in the Commonwealth of Pennsylvania. She was employed by Defendant Keystone from on or about March 1, 2006 until her termination on or about September 24, 2014. Beginning in or around the year 2006 through in or around May of 2011, Relator physically worked at Defendant Keystone's Lemoyne, PA location one day a week and at its Hanover, PA location three days a week. Starting in or around May of 2011, Relator began only working at Defendant Keystone's Hanover, PA location; working five days a week. At all times relevant, Relator's direct supervisor was Defendant Anthony Fowler.

Relator received her Pennsylvania License "Certification of Registration" as a hearing aid fitter on October 28, 2005, and her Associate's Degree in Medical Administrative Assistance in 2001.

During her employment with Defendant Keystone and at all times material hereto, Relator acted within the course and scope of her employment and agency relationship. Relator has personal knowledge of all of the Defendants' practices as a result of her duties from March 1, 2006 through September 2014 as a PA licensed hearing aid fitter and from in or around May 2011 through September 2014 as both a hearing aid fitter and as a medical insurance biller for Defendant Keystone. Relator's billing duties included receiving billing codes from Defendant Fowler

and/or Price, entering said codes into the practice management system for the hearing care industry, 'sycle.net', creating claims to bill FIP, and then reviewing the ERAs (electronic remittance advice / payments).

Defendant THE KEYSTONE HEARING INSTITUTE (hereinafter also known as "Defendant Keystone" and which does encompass the actions of Defendant Fowler) is a Pennsylvania company owned by Defendant Anthony W. Fowler, started in the year 2000, upon information and belief, with its principle place of business located at 5418 Locust Lane, Bldg. 2 Harrisburg, PA 17109-0. From at least the years 2004 through 2011, Defendant Keystone had three locations located in the following areas: Lemoyne, PA; Harrisburg, PA, location NPI #1730210246; and in Hanover, PA, location NPI#: 1922138445. In or about the year 2011, Defendant Keystone closed its Lemoyne, PA location; all of the patient files from this location were combined with the Harrisburg office files.

Defendant Keystone, through Defendants Anthony W. Fowler and Jacqueline Price also serviced patients off site at nursing homes in the local area. Upon information and belief, Medicare and Medicaid and other Federal Health Care Insurance Programs comprise over 90% of Defendant Keystone's payor source. Defendant Keystone's Department of Health Dealer Registration Number is #D00776-01.

Defendant ANTHONY W. FOWLER, Au.D (hereinafter also known as "Defendant Fowler" and does so encompass the actions of Defendant Keystone) is an adult individual residing in New Cumberland in the Commonwealth of Pennsylvania. Defendant is a board-certified audiologist and the owner, sole proprietor, managing agent and does so conduct the business of all of Defendant Keystone locations and at all times material hereto, was the servant, workmen and employee of Defendant Keystone and at all times material hereto, acting within the course and scope of his employment and agency relationship and was acting on Defendant Keystone's behalf as well as individually in all actions described in the Complaint. Defendant Fowler's PA Medical License is #AT001146L, PA Medicaid Provider Number: #001822982, Medicare UPIN: # P10140, and PA Medicare UPIN 039625, NPI #: 1841365061 with an enumeration date of 2006, and a Medicare PECOS ID #6103098892.

Defendant JACQUELINE PRICE, Au.D (hereinafter also known as "Defendant Price") is an adult individual residing in Harrisburg, Dauphin County in the Commonwealth of Pennsylvania. She is an audiologist with a Pennsylvania State Medical License of #AT001047L. Defendant Price was hired by and worked at Defendant Keystone's Harrisburg Location starting in or around May of 2011. At all times relevant she worked under the direct direction of Defendant Fowler. She was at all times material hereto, the agent, servant, workmen and employee of

Defendant Keystone and at all times material hereto, acted within the course and scope of her employment and agency relationship. Her individual Medical Insurance NPI # is 1952351868 with an enumeration date of 2006.

Defendant SONOVA HOLDING AG, (hereinafter sometimes referred to as "Defendant Sonova" and does so encompass the actions of Defendant Phonak) is an international corporation with its principal place of business at Laubisrutistrasse 28, 8712 Stafa, in the Country of Switzerland. Defendant Sonova is a manufacturer of Phonak brand hearing aids and distributes Phonak hearing aids though Defendant Phonak to Defendant Keystone and at all times material hereto, acted by and through its authorized agents, servants, workmen and employees and within the course and scope of their employment and agency relationship.

Defendant PHONAK LLC (Hereinafter also known as "Defendant Phonak" and does so encompass the actions of and direction of Defendant Sonova) is an Illinois corporation with its principle place of business located at 4520 Weaver Parkway, Warrenville, Illinois. Defendant Phonak is a member of Sonova Group which is owned by Defendant Sonova Holding AG. From at least the years 2008 through 2014, Defendant Phonak sold hearing aids to all Defendant Keystone locations in Pennsylvania through Defendant Fowler and at all times material hereto, acted by and through its authorized agents, servants, workmen and

employees and within the course and scope of their employment and agency relationship.

All Defendants are jointly and/or severally liable to the Federal Government.

III. JURISDICTION / VENUE

Venue is proper in the Middle District of Pennsylvania under 28 U.S.C. §§ 1391(b) and (c), and 31 U.S.C. § 3732(a), because Defendants can be found in and/or transact(s) business within this District.

This Court has subject matter jurisdiction over the claims alleged in this Complaint under 28 U.S.C. §§ 1331 (Federal Question), 1345 (United States as plaintiff) and 31 U.S.C. § 3732(a) (False Claims Act).

This Court has supplemental jurisdiction over the state claim pursuant to 31 U.S.C. § 3732 (b) because Defendants' Pennsylvania law violations and their violations of the FCA arise from the same transactions or occurrences. The Court also has pendant jurisdiction over Defendants' Pennsylvania Law violations because these state violations and their violations of the FCA arise out of the same nucleus of operative facts.

This Court has personal jurisdiction over all of the Defendants pursuant to 31 U.S.C. §3732(a) because all of the Defendants can be found, resides, and/or transacts business in the Middle District of Pennsylvania and because an act

proscribed by 31 U.S.C. § 3729 occurred within this District. Title 31, United States Code, § 3732(a) further provides for nationwide service of process.

Upon further information and belief, there has been no "public disclosure" of the matters alleged herein and this action is not "based upon" any such disclosure, within the meaning of 31 U.S.C. § 3730(e)(4)(A). Notwithstanding the foregoing, Relator is an "original source" of this information as defined by 31 U.S.C. § 3730(e)(4)(B) of the False Claims Act, and as such, she is expressly excepted from its public disclosure bar. *See* 31 U.S.C. § 3730(e)(4)(A) (providing that the public disclosure bar does not apply if "the person bringing the action is an original source of the information"). As pertinent here, an original source is someone "[1] who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and [2] who has voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B) (emphasis added).

Relator voluntarily informed the F.B.I. of the below allegations and again on or about March 12, 2015, Relator, with the undersigned counsel present, voluntarily disclosed the below information to Federal Bureau of Investigation, Susan E. Steinberg, Special Agent of the Harrisburg, Pennsylvania location. Ms. Steinberg was informed of the upcoming Qui Tam filing under seal.

On or about April 30, 2015, Relator, with the undersigned counsel present, voluntarily disclosed the information in this Complaint to Assistant United States Attorney of the Criminal Division, Joseph Terz. Mr. Terz was informed of the upcoming Qui Tam filing under seal. It is unknown if the DOJ has proceeded with criminal charges against any of the above named Defendants.

Relator filed a complaint concerning some of the healthcare violations that are subject to this Complaint to the Pennsylvania Department of State who in turn forwarded her complaint to the PA Dept. of Health. On April 3, 2015, the Department of Health contacted Relator and stated it found the following: "Deficiencies were found in the areas relating to the complaint under record keeping and paperwork requirements."

Upon information and belief, this Complaint is not based upon allegations or transactions that are the subject of a civil suit or an administrative civil money penalty proceeding in which the United States is already a party. 31 U.S.C. § 3730(e)(3). 31 U.S.C. § 3730(b)(5).

Pursuant to 31 U.S.C. § 3730(b)(2) contemporaneous to filing this Complaint, Relator provided the Attorney General of the United States and the United States Attorney for the Middle District of Pennsylvania with a copy of the Complaint and a written Disclosure Statement attaching substantially all material evidence and information then in Relator's possession.

Defendants' actions, as detailed throughout this Complaint, resulted in numerous violations of the FCA that occurred over a long period of time and upon information and belief, continues to occur. Further evidence of Defendants' specific violations of the FCA resides within each of the Defendant's exclusive possession and/or control.

In accordance with 31 U.S.C. § 3730(b)(2), the original Complaint has been filed in camera and will remain under seal for a period of at least 60 days and shall not be served on the Defendants until the Court so orders.

IV. APPLICABLE LAWS

A. THE FEDERAL FALSE CLAIMS ACT (31 U.S.C. § 3729)

The False Claims Act (FCA) was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government in-action and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf. Congress amended relevant provisions of the FCA in 2009 and again in 2010. See Patient Protection and Affordable Care Act, Pub. L. 111-148

§ 10104(j)(2), 124 Stat. 119, 901-02 (March 23, 2010) (amending 31 U.S.C. § 3730(e)); Fraud Enforcement and Recovery Act of 2009, Pub. L. 111-21 § 4, 123 Stat. 1617, 1621-25 (May 20, 2009) (amending 31 U.S.C. §§ 3729-33). The 2009 Act provided that it "shall take effect on [May 20, 2009] and shall apply to conduct on or after the date of enactment"—except for § 3729(a)(1)(B), which "shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act ... that are pending on or after that date." Pub. L. 111-21 § 4(f), 123 Stat. 1625 (emphases added).

The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Federal Government. .... (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information... (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

The Act allows any person having information about false or fraudulent claims to bring an action for herself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time). Based on these provisions, Relator seek through this action to recover all available damages, civil penalties, and other relief for the State and Federal violations alleged herein.

Although the precise amount of the loss from each of the Defendants' misconduct alleged in this action cannot presently be determined, it is estimated that the damages and civil penalties that may be assessed against the Defendants under the facts alleged in this Complaint amounts to over a million dollars.

Federal Law specifically prohibits providers from making "any false statement or representation of a material fact in any application for any ... payment under a Federal Health Care Program." *See* 42 U.S.C. §1320-a-7b(a)(l). Similarly, Federal Law requires providers who discover material omissions or errors in claims submitted to Medicare, Medicaid, or other Federal Health Care Programs to disclose those omissions or errors to the Government. *See* 42 U.S.C. § 1320-a-7b(a)(3). The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program, the Medicaid program, and other Federal and State funded health care programs. *See, e.g.,* 42 CFR §§ 1003.105, 1003.102(a)(l)-(2).

B. ANTI- KICKBACK ACT "AKA" (41 U.S.C. §§ 52-53)

Parties who contract or subcontract with the Federal Government are subject to the provisions of the Anti-Kickback Act. The law renders it impermissible for any person "To provide, attempt to provide, or offer to provide any kickback," and defines 'kickback' to mean "any money, fee, commission, credit, gift, gratuity, thing of value, or compensation of any kind which is provided, directly or indirectly to any prime contractors, prime contractor employee, subcontractor, or subcontractor employee for the purpose of improperly obtaining or regarding favorable treatment in connection with a prime contractor in connection with a subcontract relating to a prime contract.

C. ANTI KICKBACK STATUTE "AKS" (42 U.S.C. § 1320 *et. seq.*)

The Anti-Kickback Statute legally prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The Statute not only prohibits outright bribes and rebate schemes, but also prohibits offering inducements or rewards that has as one of its purposes inducement of a physician to refer patients for services that will be reimbursed by a federal health care program. The Statute ascribes liability to both sides of an impermissible kickback relationship.

266 The Federal Health Care Anti-Kickback Statute, arose out of Congressional
267 concern that payoffs to those who can influence health care decisions will result in
268 goods and services being provided that are not medically necessary, of poor quality,
269 or even harmful to a vulnerable patient population. To protect the integrity of FIP
270 from these difficult to detect harms, Congress enacted a prohibition against the
271 payment of kickbacks in any form, regardless of whether the particular kickback
272 actually gives rise to overutilization or poor quality of care.

273 Compliance with the Anti-Kickback Statute is a precondition to participation
274 as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA,
275 Federal Employee Health Benefit Program, and other FIP. Accordingly, claims for
276 reimbursement for inpatient or outpatient services under these programs that were
277 the result of referrals tainted by kickbacks, are false claims and are not entitled to
278 reimbursement. Providers who participate in a FIP generally must certify that they
279 have complied with the applicable Federal Rules and Regulations, including the
280 Anti-Kickback Law.

281 Any party convicted under the Anti-Kickback Statute must be excluded (i.e.,
282 not allowed to bill for services rendered) from FIP for a term of at least five years.
283 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds
284 administratively, that a provider has violated the Statute, the Secretary may exclude
285 that provider from the FIP for a discretionary period (in which event the Secretary

must direct the relevant State Agency (ies) to exclude that provider from their State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

Violation of the Anti-Kickback Statute subjects the violator to civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(7). Any person that commits an act described in 42 U.S.C. § 1320a-7b(b)(1) or (2) is also liable for damages of not more than three times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose. 42 U.S.C. § 1320a-7a(a)(7).

D. STARK LAW (42 U.S.C. § §1395nn *et seq.*)

The Stark Law prohibits a physician from making a referral to an entity for the furnishing of "designated health services" if the physician has a "financial relationship" with that entity. 42 U.S.C. § 1395nn(a)(1). Moreover, "[n]o payment may be made under [Medicare] for a designated health service which, is provided in violation of subsection (a)(1) of this section." 42 U.S.C. § 1395nn(g)(1).

Pursuant to the Stark Law, the phrase "designated health services" is defined to the phrase "financial relationship" includes a "compensation arrangement," which is defined to include any arrangement involving any remuneration between the entity and physician. 42 U.S.C. §§1395nn(a)(2)(B) and (h)(1).

Under the Stark Law, a "referral" by a "referring physician" includes the request by a physician for the item[,]" 42 U.S.C. § 1395nn(h)(5)(A), and "the request or establishment of a plan of care by a physician which includes the provision of the designated health service ...." 42 U.S.C. § 1395nn(h)(5)(B).

Compliance with the Anti-Kickback Statute and the Stark Law is a precondition to participation as a health care provider under FIP.

With regard to Medicaid, each physician must sign a provider agreement with his or her State. Although there are variations of the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the Anti-Kickback provisions. In a number of states, the Medicaid claim form itself contains an express certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal Laws.

When physicians submit bills for purchases and services under Federal Insurance, the physicians also implicitly certify that those purchases and services were not improperly influenced by illegal financial inducements.

E. EXCLUSION STATUTE (42 U.S.C. § 1320A-7)

Office of Inspector General (OIG) is legally required to exclude from participation all FIP individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses

related to the delivery of items or services under Medicare or Medicaid. .. (3) felony convictions for other health-care-related fraud, theft, or other financial misconduct; ...OIG has discretion to exclude individuals and entities on several other grounds, including misdemeanor convictions related to health care fraud other than Medicare or Medicaid fraud or misdemeanor convictions in connection with the unlawful manufacture, distribution, prescription, or dispensing of controlled substances; suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a FIP and engaging in unlawful kickback arrangements.

F. CIVIL MONETARY PENALTIES LAW (42 U.S.C. § 1320A-7A)

OIG may seek civil monetary penalties and sometimes exclusion for a wide variety of conduct and is authorized to seek different amounts of penalties and assessments based on the type of violation at issue. Penalties range from $10,000 to $50,000 per violation.

Some examples of CMPL violations include: presenting a claim that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent; presenting a claim that the person knows or should know is for an item or service for which payment may not be made; violating the

AKS; ...and making false statements or misrepresentations on applications or contracts to participate in the FIP.

G. CRIMINAL FALSE CLAIMS ACT (18 U.S.C. § 287)

Whoever makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, shall be "fined not more than $10,000 or imprisoned not more than five years, or both".

Although this is a criminal statue, Relator is entitled to a percentage of the monetary recovery through fines etc., under the alternative remedies provision of the FCA.

H. PENNSYLVANIA'S MEDICAID "FRAUD AND ABUSE CONTROL ACT" (62 P.S. § 1401, *et seq.)*

There can also be liability under the State of Pennsylvania for false or fraudulent claims with respect to Medicaid program expenditures. The statute in question prohibits false claims and statements as follows:

> It shall be unlawful for any person to: Knowingly or intentionally present for allowance or payment any false or fraudulent claim or cost report for furnishing services or merchandise under medical assistance, or to knowingly present for allowance or payment any claim or cost report for medically unnecessary services or merchandise under medical assistance, or to knowingly submit false information, for the purpose of obtaining greater compensation than that to which he is legally entitled for furnishing services or merchandise under medical assistance, or to knowingly submit false information for the purpose of obtaining authorization for furnishing services

or merchandise under medical assistance. Soliciting or receiving or to offer or pay any remuneration, including any kickback, bribe or rebate, directly or indirectly, in cash or in kind from or to any person in connection with the furnishing of services or merchandise for which payment may be in whole or in part under the medical assistance program or in connection with referring an individual to a person for the furnishing or arranging for the furnishing of any services or merchandise for which payment may be made in whole or in part under the medical assistance program. *Submitting duplicate claims for services, supplies or equipment for which the provider has already received reimbursement. *Submitting claims for services, supplies or equipment which were never provided; * Submitting a claim for services, supplies or equipment which includes costs or charges not related to the services provided to the recipient. *Submitting a claim or referring a recipient to another provider for services, supplies or equipment which are not documented in the record, are of little or no benefit to the recipient, are below the accepted medical treatment standards, or are unneeded by the recipient. *Submitting a claim which misrepresents the description of services, the dates of services, the identity of the recipient or the attending physician or the identity of the referring or actual provider; * Submitting a claim for reimbursement for a service or item at a charge higher than the provider's usual and customary charge to the general public for the same; *Providing a service or item without a practitioner's written order or the consent of the recipient, except in emergency situations. *Except in emergency situations, providing a service or item to a patient claiming to be a recipient without making a reasonable effort to verify a current medical assistance identification card, that the person is, in fact, a recipient who is eligible. *Entering into an agreement or conspiracy to obtain to obtain reimbursement or payments for which there is not entitlement. And *Making a false statement in the application for enrollment as a provider.

Penalties for Violating Pennsylvania's Medicaid False Claims Act

With one exception, violations of the Pennsylvania law constitute a felony of the third degree. For each violation there is a maximum penalty of $15,000 and up to seven years imprisonment. If an individual is convicted in any other state court or Federal court for actions that would constitute a violation of Pennsylvania's law, they may be prosecuted under Pennsylvania law for a second degree felony as well as payments of a maximum penalty of $25,000 and up to 10 years' imprisonment. Individuals convicted under Pennsylvania's law will also be required to repay the excess benefits or payments they received plus interest on the amount. Convictions also result

in preclusion of a provider from participating in the medical assistance program for a period of five (5) years from the date of conviction.

V. HEALTHCARE & INSURANCE BILLING

As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the FCA, the Federal Insurance Programs (otherwise sometimes known as "FIP") including but not limited to the below, have been damaged.

A. MEDICARE

In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program. Medicare is a federally-funded health insurance program primarily benefitting the elderly. See 42 U.S.C. §§1395c-1395i-4.

The Medicare program is administered through the Department of Health and Human Services ("HHS"), Centers for Medicare and Medicaid Services ("CMS").

To assist in the administration of Medicare Part A, CMS contracts with "fiscal intermediaries." 42 U.S.C. § 1395h. Fiscal intermediaries, typically insurance companies, are responsible for processing and paying claims and auditing cost reports.

An audiologist can receive a Medicare provider number (and payment) by applying to the local Medicare carrier. There should be no barrier to receiving a provider number as long as the audiologist is licensed or certified by ASHA.

B. MEDICAID

In 1965, Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program for the needy and the medically needy, aged, blind, disabled, and families with dependent children. 42 U.S.C. §§ 1396-1396v. This became known as the "Medicaid Program." The Medicaid Program is funded by both Federal and State monies, collectively referred to as "Medicaid Funds," with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b).

Each state is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the Department of Health and Human Services ("HHS"); HHS is an agency of the United States and is responsible for the administration, supervision and funding of the Federal Medicaid Program. The Centers for Medicare & Medicaid Services ("CMS") is the division of HHS that is directly responsible for administering the Federal Medicaid Program. Prior to 2001, CMS was known as the Health Care Finance Administration, or "HCFA."

Defendant Keystone participated with both Gateway Medicaid and Gateway Medicare Assured.

C. TRICARE/CHAMPUS

In 1967, the Department of Defense created the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), which is a federally funded medical program created by Congress. 10 U.S.C. § 1071. CHAMPUS beneficiaries include active military personnel, retired personnel, and dependents of both active and retired personnel. *Id.*

In 1995, the Department of Defense established TRICARE, a managed healthcare program, which operates as a supplement to CHAMPUS. *See* 32 C.F.R. §§ 199.4, 199.17(a). Since the establishment of TRICARE in 1995, both programs are frequently referred to collectively as TRICARE/CHAMPUS, or just "TRICARE." The purpose of the TRICARE program is to improve healthcare services to beneficiaries by creating "managed care support contracts that include special arrangements with civilian sector health care providers." 32 C.F.R. § 199.17(a)(1). The TRICARE Management Activity ("TMA") oversees this program.

The TRICARE managed healthcare programs are created through contracts with managed care contractors in three geographic regions: North, South, and West. TRICARE health services are provided through both network, and non-network, participating providers. Providers who are Medicare-certified providers are also

considered TRICARE-authorized providers. TRICARE-authorized providers are either "Network Providers" or "Non-Network Providers."

"Network Providers" include hospitals, other authorized medical facilities, doctors and healthcare professionals, all of whom enter into an agreement with the region's managed care contractor, and provide services for an agreed reimbursement rate. 32 C.F.R. § 199.14(a). "Non-Network Participating Providers" include hospitals, other authorized medical facilities, doctors and healthcare professionals who do not enter an agreement with the region's managed care provider, and are reimbursed at rates established by TRICARE regulations. *Id.*

TRICARE's governing regulations, like Medicare's and Medicaid's requirements also are based upon "medical necessity." TRICARE's governing regulations require that services provided be "furnished at the appropriate level and only when and to the extent medically necessary," and such care must "meet[] professionally recognized standards of health care [and be] supported by adequate medical documentation . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." 32 C.F.R. § 199.6(a)(5). In this respect, similar to Medicare and Medicaid, services provided at a level higher than are medically necessary are improper and violations of TRICARE. *Id.*

D. FEDERAL EMPLOYEE HEALTH BENEFITS PROGRAM

The Federal Employee Health Benefits Program ("FEHBP") is a federally funded medical insurance program for federal employees, retirees, their spouses and unmarried dependent children under age 22, administered by the Office of Personnel Management ("OPM") pursuant to 5 U.S.C. §§ 8901, *et seq.* Through the OPM, the Government contracts with private health plans or "carriers" to deliver health benefits to its employees.

Federal Agencies and their employees contribute to the Health Fund to cover the total cost of health care premiums. 5 U.S.C. § 8906. The monies from the Health Fund are used to reimburse the carriers for claims they pay on behalf of FEHBP beneficiaries. Like Medicare Part B and TRICARE, FEHBP will not cover any treatment that is not medically necessary. 5 U.S.C. § 8902(n)(1)(A).

E. BILLING FEDERAL INSURANCE PROGRAMS "FIP"

HIPAA first was created for standard transaction and code sets; meaning Payors, Medicare or other FIP, need to use the same coding system and that they could not make up their own billing codes. The vast majority of payors in this Country use Current Procedural Terminology (CPT) coding or the '92 Codes' to represent the testing or procedures the audiologists provide, ICD-9 to represent diagnoses and symptoms (ICD-10 in 2014), and HCPCS Codes to represent hearing aid related or implantable device services and product. These are the coding

systems that are required to be used across all claims. The Healthcare Common Procedure Coding System (HCPCS) starts with the letter "V" and is used for billing devises such as hearing aids, fitting and dispensing fees, and other hearing related services.

When a patient was seen at Defendant Keystone, the rendering audiologist, Defendants Fowler or Price, filled out a Master Billing Code Sheet ("Super Bills") and/or they listed the codes on a sticky note on the patient's chart and gave it to Relator or another staff member to enter into Sycle.net which would later be used to create a claim to send to the FIP for reimbursement.

From at least the years 2006 through 2011, Defendant Keystone employed Vivian Wenerick, who worked at Defendant Keystone's Lemoyne, PA office. She was in charge of billing the FIP. Upon information and belief Defendant Keystone was also fraudulently billing the FIP during this time frame.

In 2011, Defendant Keystone's Lemoyne office was closed and Ms. Wenerick stopped working for Defendant Keystone. Before Ms. Wenerick left Defendant Keystone's employ, she briefly trained Relator on billing procedures; at that time Relator began doing the billing for Defendant Keystone's two remaining office locations.

Defendant Keystone secretary, Cheryl Henson was located in the Hanover office and her duties included sometimes entering patient services and hearing aid

information into the database 'Sycle.net' (otherwise sometimes known as "Sycle"), collecting copays, faxing authorizations to FIP, and scheduling patients for both of Defendant Keystone locations.

Both Cheryl Henson and Relator worked in the Hanover office, Monday through Thursdays from 9:00 to 5:00, and Fridays from 9:00 to 12:00.

At all times relevant to this Complaint, Defendant Keystone used and continues to use an electronic data management, calendar and electronic billing system entitled "Sycle.net." This is a database system where services are entered and claims are created to send to FIP. When information was entered into Sycle correctly, all the information would populate over to the claim to be submitted.

Defendant Keystone's employees, including but not limited to Relator, would enter information into the Sycle.net system such as date patient seen, who referred the patient, who treated patient, record of hearing aid sales, any discounts given, etc. When the data was still in Sycle, prior to submission to the FIP, the fields could be altered or information could be added before being electronically submitted to a FIP for reimbursement. This is where Relator would check the claims to be sure the information was entered correctly because the claims could be rejected, even before they actually went to the payer (FIP), if something required was missing on that claim. The claims that were created in Sycle.net would then be

transferred to "Emdeon," (an electronic data interchange for electronic remittance advice or ERA's).

The claims would electronically be sent by Emdeon to the FIP payors, and then once processed, Defendant Keystone's employees, including but not limited to Relator, would view the payments Defendant Keystone received. On certain days of the week, Relator would open Emdeon, print out payments, check that the services were paid/not paid, then usually jot down a note on the printed-out payment for Defendant Keystone's secretary; indicating whether the patient needed billed for a copay and/or deductible, or if they were responsible for the balance of the hearing aids. Then the secretary or Relator would enter the payment into Sycle, print out a summary, and the secretary would bill the patient, if needed.

The NPI # of the treating "*rendering*" provider is required by FIP to be on the claim form as well as the name of the "*referring*" primary care physician.

In the event of an audit or review, the licensed provider is held responsible for the appropriateness of all claims submitted to Medicare and FIP. 42 CFR § 1001.901.

VI. FALSE CLAIMS ACT ALLEGATIONS

A. THE PRACTICE OF AUDIOLOGY

547 49 Pa Code § 45.2 defines the 'practice of audiology' as the evaluation,
548 counseling, habilitation, and rehabilitation of individuals whose communication
549 disorders center in whole or in part in the hearing function, including the
550 prevention, identification, examination, diagnosis, and treatment of conditions of
551 the human auditory system, and including the examination for, and adapting and
552 fitting of amplification or assistive devices.

553 The American Academy of Audiology (AAA), American Speech-Language
554 Hearing Association (ASHA), and the Academy of Doctors of Audiology (ADA)
555 provide guidance to their members on the rules and regulations of Medicare and
556 other FIP. Defendant Fowler belonged and, upon information and belief, continues
557 to belong to at least ASHA and AAA; as such, he was required to abide by their
558 rules, customs, ethics and directives.

559 The United States Supreme Court, in Heckler v. Cmty Health Servs., 467
560 U.S. §§ 51, 64 (1984), has found that participants in the FIP have a duty to
561 familiarize themselves with the legal requirements for cost reimbursement. The
562 Court held that "Protection of the public fisc requires that those who seek public
563 funds act with scrupulous regard for the requirements of law" therefore, Federal

Medical Insurance Programs holds health care providers "to the most demanding standards in [their] quest for public funds."

49 Pa. Code § 45.102 *Code of Ethics* provides the following:

> (a) *General.* The Board is empowered by section 5(2) of the act (63 P. S. § 1705(2)) to promulgate a Code of Ethics for speech-language pathologists, audiologists and teachers of the hearing-impaired, and the Board finds that the following rules are essential for establishing and maintaining stringent standards of professional conduct and for protecting the public interest, the Board has established the following Code of Ethics. A violation of this code constitutes unprofessional conduct under § 45.103 (relating to unprofessional conduct) or, as applicable, fraud or deceit under § 45.104 (relating to fraud or deceit), and subjects the violator to appropriate disciplinary action. (b) *Preamble.* (1) The preservation of the highest standards of integrity is vital to the successful discharge of the professional responsibilities of speech-language pathologists, audiologists and teachers of the hearing-impaired. To this end, the Board has established this Code of Ethics to safeguard the public health, safety and welfare and to assure that speech-language and hearing services of the highest possible quality are available to the people of this Commonwealth. A violation of a provision of the Code of Ethics constitutes unprofessional conduct subject to disciplinary action. Accordingly, failure to specify a particular responsibility or practice in the code should not be construed as a deliberate omission.

49 Pa. Code § 45.102(2)(h) *Principle of Ethics VI* provides the following:

> (1) A licensee shall uphold the dignity of the profession and freely accept its self-imposed standards. (2) A licensee shall inform the Board when he has reason to believe that a licensee under the act may have violated this Code of ethics. (3) Ethical proscriptions are as follows: (i) A licensee may not engage in violations of this Code of Ethics or attempt in any way to circumvent it. (ii) A licensee may not engage in

dishonesty, fraud, deceit, misrepresentation or another form of illegal conduct.

B. DEFENDANT PRICE

49 Pa. Code § 45.203 provides that (a) A business entity may provide services which require licensure, if the following conditions are met: ... (4) The business entity executes a written contract with licensed employees providing for the licensed employees' right to independent exercise of professional judgment.

At all times relevant to this Complaint, Defendant Price was a licensed audiologist. It is not known if her employer, Defendant Keystone, by and through Defendant Fowler, executed a contract with her that provided her with a right to independent exercise of professional judgment. Regardless, Defendant Price knew or should have known that she was entitled to such a right.

Defendant Price knew or should have known that Defendant Keystone, by and under Defendant Fowler's direction and/or knowledge, was committing several different and constant fraudulent actions against the FIP. Upon information and belief, Defendant Price failed to report these fraudulent actions to any government agency or FIP; although she had complete access to view any claims that were billed for her patients.

Defendant Keystone, by and through Defendants Price and Fowler, in numerous ways listed throughout this Complaint violated Federal and State Law and the Audiology Code of Ethics and was dishonest, deceitful and committed misrepresentations to both patients and the FIP.

Because of Defendant Price's actions and/or inactions, fraudulent claims to the FIP were being submitted by Defendant Keystone and ultimately paid to Defendant Keystone by the Federal Government. Once payments were received by Defendant Keystone, it paid Defendant Price.

49 Pa. Code § 45.103 provides the following:

> As used in section 10(5) of the act (63 P. S. § 1710(5)), the term ''unprofessional conduct'' includes, but is not limited to, the following types of conduct: (19) Failing to comply with the act. (20) Failing to comply with an order, rule or regulation issued or adopted by the Board, including its Code of Ethics. (21) Violating a State or Federal statute or a regulation promulgated thereunder in the *Pennsylvania Code* or the *Code of Federal Regulations* by a State or Federal agency that imposes a standard for practicing as a speech-language pathologist, an audiologist or a teacher of the hearing-impaired in this Commonwealth. The Board, in reaching a decision as to whether there has been a violation of a statute or regulation, will be guided by adjudications of the agency or court that administers or enforces the standard.

C. BILLED WRONG PLACE OF SERVICE

635 Medicare establishes that for all services the Place of Service ("POS") code
636 to be used by the physician will be assigned as the same setting in which the
637 beneficiary received the face-to-face service. *CMS Centers for Medicare and*
638 *Medicaid #7631, p. 3 (2012).*

639 On the FIP claim form, there is a specific field to enter the location where the
640 patient services were provided; this was required to be entered correctly.

641 When Defendant Keystone moved its Hanover office, which was at 1157
642 Eichelberger Street, also in Hanover, in January of 2011, Vivian Wenerick (the
643 employee who had done the billing for Defendant Keystone) was contacting some
644 of the FIPs to let the insurances know of Defendant Keystone's new address. All of
645 the claim forms Defendant Keystone used for the first half of 2011 still had the old /
646 wrong Eichelberger address listed. Once Relator agreed to help with the billing, she
647 learned that the wrong location of service was listed on the claims.

648 Approximately five months after Defendant Keystone moved its office,
649 Defendant Fowler finally filled out the correct documents which informed FIP of
650 his new office location; however, he listed the current date as the move date and not
651 the actual date; five month prior. Upon information and belief, Defendant Fowler
652 failed to use the "actual" date the office moved because he knew he was in violation
653 for not informing Medicare and other FIP of the change within thirty (30) days. At

this point Defendant Price had begun working for Defendant Keystone yet Defendant Keystone failed to include her information on the Medicare forms when filing the above documentation.

Defendant Keystone completed and submitted form CMS-8551 to Medicare stating that it started seeing Medicare patients at its Hanover location on May 20, 2011; however, Relator was present at this location between in or around January 2011 through May 20, 2011, and she had first-hand knowledge that Medicare and FIP patients were being treated at this office during that time frame.

The Pennsylvania Department of Health Bureau of Community Program Licensure & Certification/Hearing Aid Program also requires an audiology practice to register each branch location.

Defendant Price worked at Defendant Keystone's Harrisburg office on Mondays and Tuesdays. Defendant Fowler worked at this location on Wednesdays, and Gail Burcat worked at this Harrisburg location as the office receptionist / secretary Monday through Wednesdays. The Harrisburg office was not open Thursdays and Fridays.

Defendant Fowler also typically worked in the Hanover office Tuesday and Thursdays; taking off most Mondays and Fridays.

Claims that are submitted to FIP are required to have the patient place of service field completed indicating whether the services were provided in the office

or in another facility, including but not limited to, a nursing home. Relator was instructed by Defendant Fowler to always be sure that the "place of service" was listed on the claim as 'office' and never the actual nursing home location.

Anthony Fowler was usually scheduled and would see patients at the Brethren Home, in New Oxford, PA, on the first Friday of the month, over certain periods of time. Defendant Fowler also went to other nursing homes in the Hanover and Harrisburg PA areas to provide audiology services to its residents. The claims Defendant Keystone billed for these patients always had "office" as the place of service on the claims, and often included an office visit that was billed in addition to the diagnostic tests; which were never supported with documentation in the patient charts.

The patients that were also seen at other nursing home facilities in the Hanover and/or Harrisburg area including but not limited to the following patients: RCB - 03/02/12; TMF - 08/03/12; and DBM - 06/28/12.

Because Defendant Keystone submitted to FIP all nursing home claims as if Defendants Fowler or Price treated the patient's in their office, it is suspect if Defendant Keystone ever registered with the PA Dept. of Health and/or FIP that they were providing services to patients at the nursing homes.

692 Upon information and belief, Defendant Price knew that patients she
693 provided services for in nursing homes were being fraudulently billed to FIP as if
694 they were seen in Defendant Keystone's office.

695 Defendants Keystone, Fowler and Price did act and/or conspired to
696 intentionally and knowingly fail to meet the FIP conditions of participation and
697 knowingly falsified or failed to supervise the falsification of the certification that
698 they had met the conditions of participation (including each claim submitted), by
699 knowingly submitting and causing the submission and/or failing to supervise the
700 submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price
701 therefore caused the submission of claims that were false and not eligible for
702 reimbursement to FIP. By causing these claims that they knew were ineligible for
703 reimbursement to be submitted to and paid for by FIP, Defendants Keystone,
704 Fowler and Price also made, used, or caused to be made or used, false records or
705 statements material to false or fraudulent claims. Had FIP known that these claims
706 were only approved for coverage as a result of such false and fraudulent statements,
707 they would not have reimbursed for those claims. Defendant Keystone accepted
708 payment for each false claim made with these faulty conditions, paid Defendants
709 Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible
710 payments. Because FIP paid reimbursements for the resulting false claims, the FIP
711 incurred and continues to incur significant and material damages due to Defendants'

fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

D. SPLIT BILLING / WRONG DATE OF SERVICE

There were several occasions when a patient was seen at a Defendant Keystone location and paid their co-pay for that particular day. If the services for that patient were entered into Sycle on a later date, sometimes this would cause two separate dates to populate to the claim form. If this happened, the FIP would then often apply copays for each date of service causing the patient to be responsible for two copays instead of one. Defendant Keystone would collect this second copay and keep it knowing it was receiving double copays for one date of actual service; Relator brought this to Defendant Fowler's attention and he said "If the patient calls to complain, then we will address it otherwise don't waste your time resubmitting them."

On August 28, 2011, Defendant Fowler billed FIP that he saw patient CMB on this date; however, this date is a Sunday and the office is closed.

On May 30, 2013, Defendant Fowler saw patient RAB who paid a $40.00 copay, however; the claim was populated with two dates of services as if the patient was also seen on June 3rd, 2013; when Defendant Keystone entered the rest of the patient information. He billed CPT 92540 vestibular function test at $300.00 and

was paid $69.81 with a patient copay of $25.00. Patient would not have been required to pay the additional $25.00 if the claim would not have populated two dates of service.

Other examples include, but not limited to, the following patients: CMB - 08/28/11 (this date is a Sunday); RAB - 05/30/13, 06/03/13; HB - 11/12/13, 11/14/13; DC - 08/06/13, 08/07/13; GJC - 06/11/13, 06/17/13; HH - 10/16/12, 10/17/12; GGM - 06/18/13, 06/19/13; DMM - 11/08/12, 11/12/12; TM - 05/21/13, 05/24/13; AMT - 03/12/13, 03/14/13; MLT - 06/07/11, 07/07/11; and ST- 11/19/13, 11/20/13.

Upon information and belief, Defendant Price knew that Defendant Keystone was fraudulently billing second copays to patients that she treated.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that they knew were ineligible for

reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

E. MARKETING / SALES FRAUD

Defendant Keystone by and through Defendant Fowler knowingly committed and continues to commit numerous acts of marketing fraud.

49 Pa. Code § 45.102 (f) *Principle of Ethics* IV (2) *Ethical proscriptions* are as follows: (ii) A licensee's public statements providing information about professional services and products may not contain representations or claims that are false, deceptive or misleading.

49 Pa. Code § 45.102 (2)(g) *Principle of Ethics V.* provides the following:

> (1) A licensee shall maintain objectivity in all matters concerning the welfare of a person served. Accordingly, a licensee who dispenses products to a person served shall observe the following standards: (iii) A person served shall be allowed freedom of choice as to the source of services and products, in accordance with the act of May 26, 1988 (P. L. 403, No. 66) (35 P.S. §§ 449.21449.23. (iv) Price information about professional services rendered and products dispensed shall be disclosed by providing to or posting for a person served a complete schedule of fees and charges in advance of rendering services. This schedule shall differentiate between fees for professional services and charges for products dispensed.

49 Pa. Code § 45.103 provides: As used in section 10(5) of the act (63 P. S. § 1710(5)), the term ''unprofessional conduct'' includes, but is not limited to, the following types of conduct: (13) Advertising professional services and products in a manner which is false, misleading or deceptive.

28 Pa. Code § 25.215 (26) provides: Advertising a particular model, type or kind of hearing aid for sale when a purchaser or prospective purchaser responding to the advertisement cannot purchase or is dissuaded from purchasing the advertised model, type or kind, if it is established that the purpose of the advertisement is to obtain prospects for the sale of a different model, type or kind than that advertised.

> (i) In determining whether there has been a violation of this paragraph, consideration will be given to acts or practices indicating that the offer was not made in good faith for the purpose of selling the advertised product but was made for the purpose of contacting

> prospective purchasers and selling them a product or products other than that offered. Among acts or practices which will be considered in making that determination are the following: (A) The creation, through the initial offer or advertisement, of a false impression of the product offered in a material respect. (B) The refusal to show, demonstrate or sell the product offered in accordance with the terms of the offer. (C) The disparagement, by acts or words, of the product offered or the disparagement of the guarantee; credit terms; or availability of service, repairs or parts or the disparagement in another respect, in connection with it. (D) The showing, demonstrating and in the event of sale, delivery of a product which is unusable or impractical for the purpose represented or implied in the offer. (E) The refusal, in the event of sale of the product offered, to deliver the product to the purchaser within a reasonable time thereafter. (F) The failure to have available a quantity of the advertised product at the advertised price sufficient to meet reasonably anticipated demands.

1. <u>Falsely Advertised As Stocking Many Brands Of Hearing Aids</u>

In order to receive discounts and free hearing aids from Defendant Phonak, Defendant Keystone through Defendants Fowler trained Defendant Price as well as Relator to be hearing aid commissioned sales representatives and to make a series of claims about Defendant Phonak hearing aids and accessories.

When patients would inquire into buying a different brand of hearing aid, Defendants Keystone by and through Defendant Fowler would direct Relator and/or Defendant Price to persuade the patient to purchase Defendant Phonak's products.

Beginning in 2008, Defendant Keystone only sold, except on a rare occasion, one manufacturer of hearing aids; those by Defendant Phonak. Defendant Keystone

advertised that he worked with not only Defendant Phonak hearing aids, but also Widex, Oticon, Unitron, and Microtech hearing aids upon information and belief, to try and lure patients to its facility; but, when the patient arrived, only Phonak hearing aids were available and reviewed.

In many advertisements, Defendant Keystone advertised a discount on Phonak products; it is not known if Defendant Phonak compensated Defendant Keystone for these advertisements that highlighted its brand.

Although Defendant Keystone would falsely advertise it stocked several different brands of aids, Relator was not given the pricing for any of these other hearing aids except for Phonak's. Defendant Keystone only listed the pricing for Phonak hearing aids in their database 'Sycle' except for a few Rexton and Oticon aids only because 'Oticon' makes "high powered" instruments for kids.

Defendant Keystone did not keep any hearing aids in stock like he advertised, except for Defendant Phonak's products. Defendant Keystone would advertise as follows: "We work with the world's leading manufacturers" and/or "We stock aids from the leading manufacturers", but that was not the case. Defendant Keystone would only keep Defendant Phonak's hearing aids in stock, and nothing more.

When patients came in to Defendant Keystone's facility to have their hearing aids adjusted and had aids from a manufacturer other than Phonak, it was often the very first time Relator ever saw the brand; Defendant Keystone by and through

836 Defendant Fowler's direction, forced Relator to act like she was familiar with this
837 particular brand in front of the patients.

838 Because Defendant Keystone never kept up-to-date software for the other
839 manufacturers, Relator would often, after receiving the aid from a patient, have to
840 order the software and cables from that particular manufacturer. If the hearing aid
841 was not Phonak, Relator would have to work her way through the software, without
842 receiving any training, and without Defendant Fowler's direction, to try and learn
843 how to adjust the patient's hearing aids properly.

844 Defendant Keystone subscribed to a magazine called "The Hearing Journal"
845 which was mailed to the office monthly. This magazine would have just about
846 every manufacturer of hearing aids advertised with articles about the
847 features. When Relator would see hearing aids in the magazine and mention to
848 Defendant Fowler that they should carry those manufacturers, he would always say
849 "they don't make good products" or "they're crappy products". He'd also say that
850 "they'd be too expensive, and we'd have to charge the patients more than what we
851 do for Phonak." Upon information and belief, Defendant Fowler would fail to earn
852 as great a "profit" if he used another manufacture other than Phonak due to the fact
853 he was able to buy Phonak hearing aids at extreme discounts up to 50%; although
854 he would bill FIP at Defendant Keystone's full or inflated bundled price.

855 Defendants Keystone and Fowler did act and/or conspired to intentionally
856 and knowingly fail to meet the FIP conditions of participation and/or healthcare
857 rules and regulations and did knowingly falsified or failed to supervise the
858 falsification of the certification that they had met the conditions of participation
859 (including each claim submitted), by knowingly submitting and causing the
860 submission and/or failing to supervise the submission of false and fraudulent
861 claims, said Defendants therefore caused the submission of claims that were false
862 and not eligible for reimbursement from Government Healthcare Programs. By
863 causing these claims that it knew were ineligible for reimbursement to be submitted
864 to and paid for by FIP, said Defendants also made, used, or caused to be made or
865 used, false records or statements material to false or fraudulent claims. Had FIP
866 known that these claims were only approved for coverage as a result of such false
867 and fraudulent statements, they would not have reimbursed for those claims.
868 Defendant Keystone accepted payment for each false claim made with these faulty
869 conditions, and it did not reimburse the FIP for these illegal payments. Because FIP
870 paid reimbursements for the resulting false claims, they incurred and continue to
871 incur significant damages due to Defendants' fraudulent actions. Upon information
872 and belief said Defendants' fraudulent actions are continuing.

2. Falsely Advertised

873 Defendant Keystone by and through Defendant Fowler would falsely
874 advertise in the paper, online, and through delivery of brochures to different
875 doctor's offices that Defendant Keystone's practice had state of the art equipment;
876 which it did not as its equipment was several years old, and that he works with the
877 leading manufacturers; which he did not. Defendant Keystone also often advertised
878 offering a Zoom Demo.

879 The hearing aid "Zoom" feature can focus on an individual voice in a
880 crowded room, just by the direction you are facing. The "Zoom Demo" that was
881 offered, required speakers to be set up and to utilize certain "sound" files in the
882 computer software, so that you could simulate different difficult listening
883 environments so the patient could hear how much improvement it made.

884 Although Defendant Keystone received all the equipment it needed from
885 Phonak and although Defendant Keystone advertised that it performed the Zoom
886 Demo, neither of Defendant Keystone offices were set up with the speakers or
887 sound files needed to actually do the Demo. Upon information and belief
888 Defendant Keystone advertised this Demo to entice patients to come in and use
889 Defendant Keystone's hearing aid services and products.

If a patient came into Defendant Keystone and wanted a Zoom Demo, Defendants Fowler and Price as well as Relator would demonstrate this feature by utilizing other ways (using different programs in the hearing aids) and not the correct way and/or the way it was advertised to be performed.

Upon information and belief, Defendant Price failed to conduct the proper Zoom Demo on her patients.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that they knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants

Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

F. FAILED TO HAVE PATIENT SIGN UPDATED HIPAA POLICY

HIPAA requires that all patients sign a privacy policy. The patient will only need to sign the privacy acknowledgment once unless the practice, including but not limited to an audiology practice, changes its privacy policy.

In or around 2013, Defendant Keystone changed its privacy policy. Upon information and belief, Defendant Keystone did not inform and/or have the current patients sign this new policy and did not place said policy acknowledgement form in the patients' charts.

HIPAA requires that all patients' files / charts be kept under lock. Defendant Keystone failed to have locks on any of the patient files and/or storage.

Upon information and belief, Defendant Price failed to supervise her secretary, Gail Burcat, to make sure Ms. Burcat had Defendant Price's current patients sign the updated HIPAA privacy policy acknowledgement form nor did she keep her patients' files under lock.

928 Defendants Keystone, Fowler and Price did act and/or conspired to
929 intentionally and knowingly fail to meet the FIP conditions of participation and
930 knowingly falsified or failed to supervise the falsification of the certification that
931 they had met the conditions of participation (including each claim submitted), by
932 knowingly submitting and causing the submission and/or failing to supervise the
933 submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price
934 therefore caused the submission of claims that were false and not eligible for
935 reimbursement to FIP. By causing these claims that they knew were ineligible for
936 reimbursement to be submitted to and paid for by FIP, Defendants Keystone,
937 Fowler and Price also made, used, or caused to be made or used, false records or
938 statements material to false or fraudulent claims. Had FIP known that these claims
939 were only approved for coverage as a result of such false and fraudulent statements,
940 they would not have reimbursed for those claims. Defendant Keystone accepted
941 payment for each false claim made with these faulty conditions, paid Defendants
942 Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible
943 payments. Because FIP paid reimbursements for the resulting false claims, the FIP
944 incurred and continues to incur significant and material damages due to Defendants'
945 fraudulent actions. Upon information and belief said Defendants' fraudulent
946 actions are continuing.

G. UPCODING VIOLATIONS

A common type of false claim is "up-coding," which refers to using billing codes that reflect, including but not limited, to the following:

1. Billing for a more expensive service than was provided;
2. Billing for a more expensive product that was provided;
3. Billing for services that were not actually rendered;
4. Billing for services that were not medically necessary;
5. Billing for services that were performed by an unsupervised or unqualified employee;
6. Billing for services that were performed by employees who were never credentialed for participation in the Federal Health Care Program; and
7. Billing for unbundled services that were already included in a bundled price.

1. Billing For More Expensive Services Than Were Provided.

a. FAILEDTO USE OR INAPPROPRIATE USE OF MODIFIERS

An audiologist is required to use insurance code modifiers when a service is modified up or down; such as an audiologist may use the '-52' modifier (i.e.) reduced service for procedure code '92557' when they do not test both ears.

A CPT modifier provides additional information about the service rendered. This information may help to get the procedure covered by FIP or it may result in a specific payment increase or decrease.

965 Defendant Keystone through Defendant Fowler would instruct Relator and
966 other staff to enter CPT codes, often without the needed modifiers and/or added an
967 inappropriate modifier, into Sycle.net; upon information and belief Defendant
968 Fowler did so to increase the payment from the FIP.
969 An example of Defendant Keystone's actions would be it using the modifier-
970 25 at the same time with comprehensive office-exam codes in order to receive
971 payment for the visit plus a diagnostic service.
972 Upon information and belief, Defendant Price knew that Defendant Fowler
973 was coding, without the needed modifiers, the service to her patients and/or she
974 would provide a super bill to Relator which failed to document modified codes.
975 Defendants Keystone, Fowler and Price did act and/or conspired to
976 intentionally and knowingly fail to meet the FIP conditions of participation and
977 knowingly falsified or failed to supervise the falsification of the certification that
978 they had met the conditions of participation (including each claim submitted), by
979 knowingly submitting and causing the submission and/or failing to supervise the
980 submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price
981 therefore caused the submission of claims that were false and not eligible for
982 reimbursement to FIP. By causing these claims that they knew were ineligible for
983 reimbursement to be submitted to and paid for by FIP, Defendants Keystone,
984 Fowler and Price also made, used, or caused to be made or used, false records or

statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

b. FAILED TO HAVE APPROPRIATE TEST AREA (SOUND LEVEL METER)

Pennsylvania State Code requires an audiology facility to have an appropriate hearing test area, the ambient noise level of which shall have a documented readout of 55 dB or lower on the A scale of a sound level meter. The test area shall meet at all times the specifications detailed in the *Maximum Permissible Ambient Noise Levels for Audiometric Tests Rooms* (ANSI S3.1-1999; American National Standards Institute, 2003).

When the air conditioner or heating system was on in a Defendant Keystone site, the dB was over the maximum allowed at some frequencies.

Upon information and belief, Defendant Price also treated patients without an appropriate hearing noise level test area.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that they knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

c. FAILED TO CALIBRATE EQUIPMENT

It is essential that audiometric equipment be calibrated, be functioning properly, and be used in an acceptable test environment to assure accurate test results.

There were several occasions when a Defendant Keystone headphone would go bad during service to a patient. Relator noticed several instances when Defendant Fowler replaced the broken headphone without first doing the required recalibration of the audiometer.

28 Pa. Code § 25.209 *Facilities, procedures and instrumentation* provides:

> (a) *Facilities*. A registrant shall engage in the practice of fitting or selling a hearing aid only if the registrant provides: (1) An appropriate test area, the ambient noise level of which shall have a documented readout of 55 dB or lower on the A scale of a sound level meter. (2) A selection of hearing aid models, supplies and accessories to provide for the immediate needs of hearing aid users or prospective hearing aid users. (b) *Procedures*. A registrant shall satisfy the following: (1) The registrant shall sell a hearing aid only if within 6 months before the sale an examination of the prospective hearing aid user was conducted using pure tone air conduction, bone conduction and speech audiometry tests. This requirement does not apply when the registrant is replacing a hearing aid with another of the same make, model and response. The registrant shall sell a hearing aid replacing another of the same make, model and response only if within 12 months before the sale an examination of the prospective hearing aid user was conducted using pure tone air conduction, bone conduction and speech audiometry tests. The registrant shall verify that the tests were performed by an individual authorized by law to do so. The registrant may rely on a representation by the physician, audiologist or fitter who performed or supervised the tests that the individual who performed the tests was authorized to do so. (2) The registrant shall: (i) Perform air conduction tests for hearing level thresholds at frequencies of 250 Hz, 500 Hz, 1,000 Hz, 2,000 Hz, 4,000 Hz and 6,000 Hz

or 8,000 Hz, with masking if necessary. (ii) Perform bone conduction tests for hearing level thresholds at frequencies of 500 Hz, 1,000 Hz, 2,000 Hz and 4,000 Hz, with masking if necessary. (iii) Maintain records of the test results for each ear for 7 years. (iv) Perform a speech reception or speech awareness threshold test using an electronic speech audiometer with head or insert ear phones. (v) Perform a word discrimination or other speech intelligibility test for conversational level speech using an electronic speech audiometer with head or insert ear phones. (3) The registrant shall sell a hearing aid only if the hearing aid is fitted to the wearer to ensure physical and operational comfort and improvement in hearing function is demonstrated and documented in at least one of the following areas: speech detection, speech awareness levels, speech intelligibility, orientation or speech reception threshold. (c) *Instrumentation.* A registrant shall satisfy the following: (1) All test instruments shall be calibrated once each year or more often if necessary to meet current American National Standards Institute standards for pure tone and speech audiometry as identified by 1996 A.N.S.I. standards or applicable succeeding A.N.S.I. Standards. (2) Instruments transported to test sites shall be calibrated to the standard set forth in paragraph (1) every 6 months, or more frequently as needed. (3) Calibration shall be performed by a qualified individual other than the owner. (4) A signed certificate identifying the most recent date of calibration shall be maintained for inspection by the Department.

Upon information and belief Defendant Fowler also failed to re-calibrate the equipment when the equipment moved to the Harrisburg office, a nursing home or back to the Hanover office.

Upon information and belief, Defendant Price knew the equipment delivered by Defendant Fowler that she used on her patients was not calibrated as required.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that

they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that they knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

2. Billing For A More Expensive Product Than Was Provided

a. BILLING FOR HEARING AIDS AT AN INCREASED PRICE

On or around September 5, 2014, Defendant Fowler requested his secretary Cheryl Henson to write down recent payments that Defendant Keystone received from each of the different FIPs to determine how much each would pay on hearing aid benefits; Defendant Keystone would routinely bill each FIP a different and/or inflated amount for a hearing aid depending on what that insurance was known to pay.

There are several types of hearing aids; BTE-behind the ear, ITE- in the ear, CIC- completely in the canal, and RIC- receiver in canal. To prescribe a certain type of hearing aid is sometimes a patient preference, but some patients can't wear certain styles because of previous surgeries, or size of canal, deformities, problems with excessive wax, or a hole in the eardrum etc. It also depends on their hearing loss. Smaller hearing aids will only have a certain amount of "gain" or "volume" that is available, so if someone has a moderate to severe loss, they will need to go with an aid such as a RIC that will be capable of giving them the volume that they need. RIC hearing aids can fit a variety of hearing losses, from mild to moderately severe. Patients that start with a CIC will usually at some point have to upgrade to something larger, once their hearing loss reaches a certain decibel level.

Hearing aid prices vary depending on the circuits in them. There are typically four levels of technology for each hearing aid manufacturer. They all make an "Entry Level" or "Basic Level" product, which is the cheapest. Then there is "Standard Level", which is a little more expensive, then "Advanced" which is even more expensive, and the most expensive level would be "Premium". Each level of technology has different "features". The more "features", the more expensive. You can get any style of hearing aid in all different price levels.

Defendant Fowler typically sold the cheaper models to his patients. He seldom put patients in better technology; he would make the same profit either way. It is unknown at this time why Defendant Fowler would not offer a higher level hearing aid to some of his patients who would often benefit greatly from these increased features.

Defendant Keystone often bill the FIP an increased price for whatever level model was sold or he would sell a certain model but bill for a different model knowing he would get a higher reimbursement; such as selling a BTE but billing for a CIC.

Several of Defendant Fowler's patients came in to see Relator when they were having issues with their hearing aids and would question the type or level of hearing aid they bought from Defendant Keystone. Patients would say to Relator:

"Tony told me these were the best ones"; and yet Relator would discover that the patient would only be wearing either a Basic or Standard Level product.

When Defendant Keystone would bill hearing aids to the FIP, the insurance does not know what level of technology it is as the codes are categorized by the style (BTE, ITE, RIC, and CIC).

Several of the FIP pay for a certain percentage of a hearing aid purchase and accompanying services. Defendant Keystone would inflate the hearing aid prices at different amounts depending on the percentage that the particular Federal Insurance Program paid. The same hearing aid and services would be billed one price for Tricare Insurance and perhaps a different price to Medicaid.

The price of the hearing aids were not always billed at the prices quoted to the patient. Below are examples; however, Relator knows of several other claims, not listed below, in which aids were quoted / purchased at a discounted price, only to be billed to FIP at the normal or an inflated cost:

WC - 10/27/10, V5261- billed at $9000.00 (most expensive aids sold, are sold at $6000.00), V5110- billed at $795.00 (normally billed at $495.00), V5266- billed at $195.00 (normally billed at $60.00).

KKH - 04/16/14, V5014-billed at $100.00 (this code is normally used for hearing aid repairs, when the aids need sent out, but was used for a tube change, which is normally a $10.00 fee charged for changing both tubes).

RCJ - 02/03/11, V5261-billed at $7200.00 (normally these aids are $5800.00).

KMK - 07/01/10, patient was fit with a new ear mold and billed a $475.00 dispensing fee, in addition to the cost of the ear mold, which is normally billed at $75.00 only.

SM - 02/21/11, hearing aids were billed at $3500.00 each, Relator is not sure what aids these were, but the most expensive ones listed at Defendant Keystone's facility are $3000.00 each. V5090- dispensing fee was billed at $795.00, normally billed at $275.00, payment was $477.00. Hearing aid batteries- V5266, billed at $140.00, with payment of $84.00, batteries were free with hearing aid purchases for 3 years at the time of this sale. Fitting fee -V5011, was also billed and is normally included with the bundled quote for the hearing aids.

JJS - 10/15/13, 10/16/13, V5257 LT/RT-purchased aids that are normally $2100.00 each, billed to insurance at $2500.00 each.

RS - 09/25/12, V5261 aids sold at $3000.00, billed to insurance at $4000.00.

TT - 10/08/10, Hearing aids V5261, billed at $10,000.00, the most expensive set of hearing aids was $6000.00 on the price list at Defendant Keystone's facility. Batteries billed at $140.00, with payment of $84.00, when they were free for 3 years with all hearing aid purchases at the time of sale. Fitting fee –V5011, also billed and should have been included with the bundled amount charged for the hearing aids.

RTr - 01/03/11, Hearing aids billed at $5000.00; Relator is not sure which aids these were. V5090, dispensing fee billed at $795.00, normally is billed at $275.00. Batteries, free for three (3) years at the time, were billed at $140.00, with payment of $84.00. Fitting fee -V5011, also billed and should have been included in the bundled price quoted for the aids.

There is a Male Patient noted that the payment received from Workers Compensation on 01/26/12was $6533.04. He was fit with hearing aids that are normally priced at $4200.00.

Claims were billed by Defendant Keystone to FIP with the CIC, CPT code V5258 (completely in the canal aid) instead of BTE, CPT code V5261 (behind the ear aid), when it was known that insurance reimbursement would be greater for the CIC code. The patients listed below were not fit with CIC aids but billed for the CIC to the FIP: MPD - 03/01/11; PPK - 03/28/11; MJL - 03/02/11; BJL - 05/04/12;

KP - 06/18/13; DLR - 11/07/12 (also discounted aid cost to patient, but was billed to insurance at higher cost); and FS - 08/16/12.

Upon information and belief, Defendant Price knew or should have known that Defendant Keystone was billing FIP a higher amount for the hearing aids than the cost of what she quoted to her patients.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible

payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

b. SELLING USED / WORN / DIRTY HEARING AIDS AS NEW

Audiologists have been enjoined from violating a provision of the Unfair Trade Practices and Consumer Protection Law (73 P. S. §§ 201-1—209-6) or being subject to a final order of the Federal Trade Commission, the Health Department, or the Food and Drug Administration of the United States Department of Health and Human Services, concerning the sale or offering for sale of an unsafe, unhealthful or worthless hearing device or for engaging in conduct which has the tendency to mislead or deceive.

28 PA Code § 25.215 (13) provides: Using, causing or promoting the use of any advertising matter, promotional literature, testimonial, guarantee, warranty, label, brand, insignia or any other representation, however disseminated or published, that is misleading, deceiving, improbable or untruthful, such as a misrepresentation.

28 PA Code § 25.215 (23) provides: Making a representation either directly or indirectly that a hearing aid or part thereof is new, unused or rebuilt when that is not true.

> (i) In the marketing of a used hearing aid or a hearing aid which contains used parts, a registrant shall make full and non-deceptive disclosure of the fact in advertising and promotional literature relating to the product on the container, box or package in which the product is packed or enclosed. The required disclosure may be made by use of words such as ''used,'' ''second-hand,'' ''repaired'' or ''rebuilt,'' whichever applies to the product involved, and it shall appear on a tag physically attached to a hearing aid. (ii) A registrant may not misrepresent the identity of the rebuilder of a hearing aid. If the rebuilding of a hearing aid was done by other than the original manufacturer, a registrant shall disclose the fact wherever the original manufacturer is identified.

The Food and Drug Administration (FDA) regulates the conditions for sale of specific medical devices, including hearing aid devices. These regulations are summarized below:

- Prospective hearing aid users must obtain a medical clearance from a physician (preferably one who specializes in diseases of the ear) prior to being fit with amplification. The medical clearance must have occurred in the last six months. If the prospective user is over 18 years of age, they may waive this medical clearance and, instead, complete a medical waiver. The medical waiver must use language provided by the FDA.
- Prospective hearing aid users under the age of 18 years of age obtain a medical clearance from a physician (preferably one who specializes in diseases of the ear) prior to being fit with amplification. The medical clearance must have occurred in the last six months. Neither the child or their parent or guardian may waive this medical clearance requirement.

- Hearing aid users must be provided with the User Instructional Brochure provided by the hearing aid manufacturer. Review of this brochure must take place orally or in the predominate method of communication used during the sale.
- Medical waivers and medical clearances must be retained by the dispenser for a minimum of three years. (Note: HIPAA requires patient medical records be retained for a minimum of six years after the last date of service).

21CFR § 801.421 (2014)

Defendant Keystone and Defendant Phonak had an agreement that for so many hearing aid purchases, Defendant Phonak would give Defendant Keystone so many free hearing aids and accessories. If Defendant Keystone would have returned any of the hearing aids to Defendant Phonak, it may have compromised how many free products it was entitled to.

49 Pa. Code § 45.102 (d) *Principles of Ethics II.*

> (1) A licensee shall hold paramount the welfare of persons served professionally. (v) A licensee shall take all reasonable precautions to avoid injuring a person in the delivery of professional services. (vi) A licensee shall evaluate services and products rendered to determine their effectiveness.

A patient, who had bought a hearing aid from Defendant Keystone, has thirty days in which to return their hearing aid to Defendant Keystone for reimbursement. Defendant Keystone was required to return the hearing aid to Defendant Phonak for credit and contact the FIP, which was initially billed, for that service / product.

1278 Before the 30-day deadline, when a hearing aid was returned to Defendant
1279 Keystone, it was often not returned to Phonak; it was put back into stock.

1280 When a hearing aid was returned, regardless of when it was returned,
1281 Defendant Fowler would often put the hearing aid, without cleaning it, back into its
1282 stock for resale as a new product.

1283 Defendant Keystone would proceed to sell the used hearing aid as 'new' to
1284 an unsuspecting patient. The hearing aids are all identified by a different serial
1285 number which is then assigned to each patient's name so that warranties can be
1286 determined. Defendant Fowler would often discount these "used" aids by varied
1287 amounts. The patients; however, were not informed that the hearing aids were
1288 previously worn or "used". Patients were sometimes told they were given a "deal"
1289 on the aids, and often, the "listed" price was not disclosed to the patients, so they
1290 were unaware that the aids were discounted.

1291 The price billed to FIP would depend on what price Defendant Fowler
1292 indicated to be used, via typically on a sticky note on the patient chart. Nothing was
1293 consistent or "standard" practice when this occurred. It was always whatever
1294 Defendant Fowler "noted" to be billed. Notes on patient charts would state, "Bill at
1295 usual/normal price". Hearing aids were often discounted simply because they were

in 'stock' for a while and Defendant Fowler would want to get rid of them because newer models were available.

Defendant Keystone would often bill the used hearing aid to the patient's FIP as a 'new' hearing aid without the discounted cost.

On occasion Relator would take what she thought was a new hearing aid from the stock to sell to a patient, only to discover the hearing aid still had ear wax on it from its previous owner.

The below patients, identities provided to the Attorney General, purchased a certain serial numbered hearing aid(s), returned them, and then the same serial number was then sold as 'new' to another patient. No two hearing aids from the same manufacturer can have the same serial number; they are all identified by a different serial number so that warranties can be determined. Defendant Fowler would discount some aids however much he wanted; although he would bill the FIP a different and usually an inflated amount:

DJS, in the Hanover office, purchased two (2) Phonak Audeo Smart III's, with serial numbers: 1130X0GH3 and 1130XOGH4, on 08/22/2011. He returned them on 11/01/2011. These same hearing aids, with the same serial #s, were then sold to another patient, also in the Hanover office, on 01/19/2012, with a $200.00 discount.

A patient, in the Hanover office, purchased two (2) Phonak Audeo Smart III's, with serial numbers: 1112X0HFV and 1112X14AR, on 07/21/2011. She returned them on 09/30/2011. A male patient, in the Hanover office, purchased 2 Audeo Smart III's, serial numbers: 1112X0HFV and 1137X0JJE, on 10/04/2011. He kept both aids, and was given a $1200.00 discount off the set. SLM, in the Harrisburg office, purchased 1 Phonak Audeo Smart III, with serial number 1112X14AR, on 12/07/2011. She was given a $300.00 discount and she did keep the aid.

GAC, in the Harrisburg office, purchased one (1) Phonak Cassia micro M, on 05/18/11, with serial number: 1111X0DET. He returned the aid on 06/14/11. On 08/10/11, a female patient, also in the Harrisburg office, purchased two (2) Phonak Cassia micro M's, with serial numbers: 1111X0DET and 1111X0DER, with a $1200.00 discount off the pair, and she did keep the aids.

A female patient, in the Hanover office, purchased two (2) Phonak Milo Plus micros on 08/20/12, with serial numbers: 1226X016U and 1226X016V. She returned the aids on 09/11/12. These same aids, with the same serial #s were then sold to a male patient, in the Harrisburg office, on 10/17/12, with a $1200.00 discount off the pair. He kept the aids.

A male patient, in the Harrisburg office, purchased two (2) Phonak Audeo Smart IIIs with serial numbers: 1227X0FG3 and 1229X0NRY, on 09/26/12. He

returned them on 11/28/12. These same aids, with the same serial #s were then sold to a male patient, in the Hanover office, on 1/16/13. He was given a $600.00 discount off the set, and did keep the aids.

A male patient, in the Hanover office, purchased two (2) Bolero Q50's, with serial numbers: 1303X112E and 1303X112F, on 02/05/13. He returned them on 02/19/13. These same aids, with same serial #s were then purchased by a female patient, also in the Harrisburg office, on 03/01/13. She was given a $200.00 discount off the set, and did keep the aids.

A male patient from the Hanover office, purchased two (2) Audeo Q50's, on 05/14/13, with serial numbers: 1310H08GT and 1310H08GU. He returned them on 06/20/13. The same aids, with same serial #s were then sold to a female patient, in the Harrisburg office, on 08/21/13. She also returned them, on 10/16/13. The same aids, same serial #s were then sold to female patient, in the Hanover office, on 02/20/14. She was given a $600.00 discount, and did keep the aids.

A female patient, from the Harrisburg office, purchased two (2) Phonak Audeo Q50s on 05/29/13, with serial numbers: 1315H0GPC and 1315H0GPD. She returned one aid, serial # 1315H0GPC, on 06/17/13. This same aid was then sold to a female patient, who was Relator's patient in the Hanover office. She cancelled her fitting scheduled on 08/19/13, so the aid was again put back into stock. This same

aid, with serial # 1315H0GPC, was sold to another female patient, in the Hanover office, with a discount of $250.00, on 10/15/13. She kept the aid.

A male patient, in the Harrisburg office, purchased two (2) Phonak Audeo Q50s with serial numbers: 1310H08F0 and 1310H08F1, on 05/29/13. He returned the aids on 07/24/13. These same aids, with same serial #s were then sold to a female patient, in the Hanover office, on 08/05/13, with a $600.00 discount. She kept the aids.

A male patient, in the Hanover office, purchase two (2) Phonak Audeo Q30's, with serial numbers: 1333X11RX and 1333X11RY, on 09/17/13. He returned them on 11/12/13. The same aids, with same serial #s, were then purchased by another male patient, in the Hanover office, on 11/21/13. Normally, these aids are sold at $1800.00 each, $3600.00 total. They were sold to a male patient at $2000.00 each, totaling $4000.00. He did keep the aids.

Upon information and belief, Defendant Price knew that she was selling used hearing aids as 'new' to her patients without disclosing this fact to the patient and allowing her sales to be billed to the FIP as a new product and/or at an inflated cost.

Defendants Sonova, Phonak, Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and/or healthcare rules and regulations and did knowingly falsified or failed to supervise the falsification of the certification that they had met the

conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, said Defendants therefore caused the submission of claims that were false and not eligible for reimbursement from Government Healthcare Programs. By causing these claims that they knew were ineligible for reimbursement to be submitted to and paid for by FIP, said Defendants also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Keystone and Price with this money, and it did not reimburse the FIP for these illegal payments. Because FIP paid reimbursements for the resulting false claims, they incurred and continue to incur significant damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

c. SELLING HEARING AIDS THAT WERE OBTAINED FOR FREE

Defendant Keystone would routinely order hearing aids in a bulk order from Defendant Phonak, usually purchased with an incentive such as "buy 10 get 2 free", or because Defendant Phonak would include free accessories with its purchases. This information was not disclosed to the patients other than at times

1393 when it was advertised that "free accessories were offered with certain levels of
1394 technology purchased." The free accessories were also sold to patients and billed to
1395 FIP in many instances as well; it always depended on what Defendant Fowler
1396 wanted.

1397 Upon information and belief, Defendant Price knew or should have known
1398 that Defendant Keystone was fraudulently billing the FIP for free hearing aids
1399 and/or accessories that she sold to her patients.

1400 Defendants Keystone, Fowler, Sonova, Phonak, and Price did act and/or
1401 conspired to intentionally and knowingly fail to meet the FIP conditions of
1402 participation and knowingly participated in a kickback scheme, falsified or failed to
1403 supervise the falsification of the certification that they had met the conditions of FIP
1404 participation (including each claim submitted), by knowingly submitting and
1405 causing the submission and/or failing to supervise the submission of false and
1406 fraudulent claims, Defendants therefore caused the submission of claims that were
1407 false and not eligible for reimbursement to FIP. By causing these claims that they
1408 knew were ineligible for reimbursement to be submitted to and paid for by FIP,
1409 Defendants also made, used, or caused to be made or used, false records or
1410 statements material to false or fraudulent claims. Had FIP known that these claims
1411 were only approved for coverage as a result of such false and fraudulent statements,
1412 they would not have reimbursed for those claims. Defendant Keystone accepted

payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

d. FRAUDULENTLY BILLED FOR REPLACEMENT RECEIVERS

Receivers are components that attach to BTE hearing aids and extend into the ear. When a patient's receiver breaks, and the warranty had expired, they return it to Defendant Keystone and then buy another receiver. Defendant Fowler would wait until he collected a bunch of broken receivers that were out of warranty, and then fraudulently return them to Phonak as being under warranty. He would do this by searching his database and randomly pulling the serial number off hearing aids that he sold recently to other patients and that were still under warranty. Phonak would then replace all the broken receivers for free. When Defendant Keystone would receive these free receivers, it would proceed to sell them to different patients and fraudulently bill the FIP.

Defendants Keystone and Fowler did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and/or healthcare rules and regulations and did knowingly falsified or failed to supervise the

falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, said Defendants therefore caused the submission of claims that were false and not eligible for reimbursement from Government Healthcare Programs. By causing these claims that it knew were ineligible for reimbursement to be submitted to and paid for by FIP, said Defendants also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, and it did not reimburse the FIP for these ineligible payments. Because FIP paid reimbursements for the resulting false claims, they incurred and continue to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

3. Billing For Services That Were Not Actually Rendered

a. FITTING HEARING AIDS WITHOUT REQUIRED TESTS

49 Pa. Code § 45.102 (2)(g) *Principle of Ethics V.*

> (1) A licensee shall maintain objectivity in all matters concerning the welfare of a person served. Accordingly, a licensee who dispenses products to a person served shall observe the following standards:

(v) A licensee shall evaluate products dispensed to a person served to determine their effectiveness.

The Codes '92557' (Comprehensive Audiometry) or 'V5010' (Assessment for Hearing aid), were fraudulently billed to FIP, because Defendants Fowler and/or Price did not complete the tests. '92557' is not a complete test when bone conduction or speech reception is not done, or when a report was not completed to give to the referring physician. '92557 'should not be billed when patients are tested for hearing aid selection, V5010 should be used in these cases, but requires additional measures, such as MCL and UCL, to be completed and noted on the audiogram; which was usually not done. V5010 is not a paid benefit of Medicare patients, so it is assumed that this is the reason the tests were often billed as '92557' instead.

Defendant Keystone would bill the FIP at code 'V5010' which is an assessment for hearing which includes completing MCL and UCL; however, Defendants Fowler and/or Price would not actually perform said assessment. The code 'V5010' was often billed solely based on known or anticipated payment from the FIP. It was not a matter of checking the audiogram to see if it was completed prior to billing, V5010 was added to services charged, when there was a known payment from particular FIPs or when it was anticipated that payment would/may be made by the FIP. Examples are, including but not limited, the following patients

treated by Defendant Keystone: DRA- 07/30/13- 92557; EA - 06/29/12- V5010; WA - 06/29/12- V5010; CEB - 11/04/13- V5010; JPB - 09/27/11, 9/13/12, 08/20/13- three separate claims with 92557; RMB - 08/13/13- 92557; BB - 08/10/11- V5010; GJB - 04/22/10- V5010; RCBL - 05/27/10- V5010; EB - 01/31/12- V5010; FAB - 09/11/12- V5010; JLB - 08/23/10- V5010; DEB - 04/06/10- V5010; EJB - 07/15/10- V5010; and ALB - 08/28/13- V5010; Relator also has information on violations occurring on approximately seventy (70) other patients.

Upon information and belief, Defendant Price also failed to conduct the proper tests and/or complete the tests properly on her patients and knew that Defendant Keystone was fraudulently billing the FIP as if the tests were completed.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that they knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone,

Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

b. FAILED TO USE REAL EAR PROBE TEST

Defendants Fowler, and upon information and belief, Defendant Price would fail to use "Real Ear Probe Testing" when seeing their patients.

Real Ear Probe Testing is a test to determine which setting is best for a hearing aid to amplify speech across different frequency ranges. This test takes 5-10 minutes. This test is done to verify that the settings in the hearing aid are accurate while the hearing aid is being worn by the patient. Almost every place that dispenses hearing aids does this. Defendant Keystone did have the equipment to do this, but Defendant Fowler never used it.

A patient confronted Relator and asked why Defendant Keystone did not conduct a real–ear probe. Relator repeatedly questioned Defendant Fowler about using it, because it was never set up nor was Relator ever trained to use it. Defendant Fowler stated "Just tell the patient that it's done in the software"; which is not the case. He also stated to Relator: "I've got the equipment, I just don't use it".

There are some things in the software designed to maximize the fitting, but it is not equivalent to the real ear probe testing that should be done for everyone who is fit with hearing aids.

According to many audiology articles and courses Relator has taken, Real Ear Probe Testing is something that is required to be conducted. When this isn't done, the settings in the hearing aid are based off of the patients hearing test results, which are obtained using only headphones.

Real Ear Probe Testing is performed by setting the tip of the hearing aid in the ear canal, closer to the eardrum while the patient is wearing the hearing aids. It is done so that the patient is not hearing certain things too loud, and so that they are hearing at comfortable levels. Hearing aids can be adjusted for certain issues, but doing this test is the best way to get the patient's hearing optimal, without the need

to make several adjustments over a period of every few weeks to have their aids adjusted for things that are bothersome to them.

Upon information and belief, Defendant Fowler knowingly failed to do this "once and usually done" test so that Defendant Keystone could instead bill FIP for each date the patient would now have to come in afterwards to have their hearing aid(s) adjusted.

Upon information and belief, Defendant Price also failed to conduct Real Ear Probe Testing on her patients as required and knew that Defendant Keystone was billing the FIP as if she had conducted this Probe.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that they knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or

statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

c. FAILED TO CONDUCT A COMPREHENSIVE OFFICE EXAM

An audiologist may not select a code for a patient for the sole purpose of obtaining reimbursement.

The CPT Codes for an 'office visit' Evaluation & Management ("E/M") services range from Level I, for the least complicated low severity services to Level V, for complex services for cases of high severity; the Federal Healthcare Programs reimburse the higher levels of E/M services at a significantly higher rate.

Defendants Fowler and Defendant Price were aware of, or should have been aware of, the conditions for repayment under all of the Federal Insurance Programs referred to in the preceding paragraphs.

Medicare Part B permits providers to use either of two Evaluation and Management ("E/M") Documentation Guidelines. CPT Codes are used to report E/M services. While providers must insure that the Guidelines' requirements for the individual CPT Codes are met when selecting the appropriate CPT Code, medical necessity for the service must also be met. According to Medicare, it is not medically necessary or appropriate to bill a higher level of E/M 'office visit' service when a lower level of service is all that is medically necessary. Documentation in the medical record must support the level of service chosen.

Medical Necessity of E/M services is generally expressed in two ways, by the frequency of services and the intensity of service – which corresponds to the CPT level. The provider's documentation of E/M services reported to Medicare must demonstrate that both the frequency and the intensity of the E/M service were appropriate considering the nature of the patient's complaint and condition. Medicare's determination of medical necessity is separate from its determination that the E/M service was rendered as billed.

Medicare judges the provision of the service based on CPT E/M Code definitions and the CMS E/M Service Documentation Guidelines.

The CPT Codes that govern E/M services are as follows: for new patients, 99201 to 99205; and for established patients, 99211-99215. Each level reflects an increased level of acuity of the patient's presenting complaint; the number of

physical systems evaluated and managed during the encounter; the acuity and/or duration of the problems evaluated and managed; and the complexity of documented comorbidities that have clearly influenced the physician's work. The CPT Codes thus reflect an increasing level of complexity of "medical decision making."

CPT Code 99212 is defined as an office or other outpatient visit for the evaluation and management of an established patient which requires at least two (2) of these three (3) key components: a problem focused history; a problem focused examination; or straightforward medical decision making. Usually the presenting problems are self-limiting or minor. Physicians typically spend ten (10) minutes face-to-face with the patient and/or family.

CPT Code 99213 is defined as an office or other outpatient visit for the evaluation and management of an established patient which requires at least two (2) of these three (3) key components: an expanded problem focused history; an expanded problem focused examination; medical decision making of low complexity. Usually the presenting problems are self-limiting or minor. Physicians typically spend fifteen (15) minutes face-to-face with the patient and/or family.

CPT Code 99214 is defined as an office or other outpatient visit for the evaluation and management of an established patient, which requires at least two (2) of these three (3) key components: a detailed history; a detailed examination;

and medical decision making of moderate complexity. Counselling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problems are of moderate to high severity. Physicians typically spend twenty-five (25) minutes face-to-face with the patient or family. An office visit qualifying for CPT Code 99215 is identical, except that it involves medical decision-making of high complexity and typically involves a forty (40) minute patient visit.

Medicare makes clear that in order to bill the highest levels of visit codes, the visit must include a comprehensive history that includes a review of all of the systems and a review of a complete past family and social history, whether taken at that visit or a prior visit.

To bill a FIP for an office visit, a comprehensive patient history intake must be conducted by an audiologist. This intake includes items such as patient medications, past surgeries, etc. This information would then be stored in the patient's chart. Audiologists are only allowed to bill for this service under CPT 99211. They are not allowed to bill under CPT 99201, 99202, 99211, or 99212 because only physicians (not audiologists) can bill under those codes. Although allowed, it is very rare that an audiologist would bill a FIP under the CPT 99211 because usually it is not necessary for treatment and the referring provider would

already have this information. This code is never allowed to be billed when the appointment is related to hearing aid fitting and/or services.

Medicare will not reimburse an audiologist for a comprehensive office visit "E/M"; however, other FIPs may reimburse. Defendant Keystone would bill the FIP, sometimes under CPT Code 99211, the code audiologists are allowed to use, and other times under a code only physicians may use; depending upon what code that FIP was known to reimburse for.

On July 30, 2013, Defendant Fowler treated patient DRA and billed the FIP for $152.00. This charge is broken down as $55.00 for office visit under CPT Code 99211 and $97.00 for a comprehensive audiological exam CPT Code 92557. This patient did not have the required notes in her chart to allow for billing of an "office visit." Relator alleges that Defendant Fowler failed to conduct the office visit intake that he later billed the FIP for. This patient's chart notes also document that Defendant Fowler failed to conduct a comprehensive audiological exam. He only conducted a simple screening over the top of a previous test that Relator conducted on this patient on March 5, 2008. He failed to conduct the rest of the test which he billed the FIP for. Defendant Keystone billed FIP $152.00 for both services and received payment of $62.94.

On May 29, 2014, Defendant Fowler saw patient DWA. Defendant Keystone billed FIP for an office visit under CPT Code 99201 (a code an audiologist is not allowed to bill under) for $65.00. Medicare denied payment based on this code. Defendant Keystone forwarded this bill to Highmark Blue Shield. Patient's chart fails to have documentation which shows a comprehensive history of the patient was taken. This lack of documentation should not have allowed Defendant Keystone to bill for an office visit.

On May 19, 2010, Defendant Fowler saw patient EFA and billed FIP for $65.00, CPT 92506 (a code not allowed to be billed by an audiologist) as an evaluation of speech, language, voice or communication. Defendant Fowler did not conduct this exam and Defendant Keystone only billed under this code because it knew that otherwise this FIP would not pay it for an office visit.

On December 14, 2010, Defendant Fowler saw patient DMA and billed FIP for CPT Code 92506 U9 at $65.00 and was paid $47.25 (a code not allowed to be billed by an audiologist) as an evaluation of speech, language, voice or communication. Defendant Fowler did not conduct this exam and Defendant Keystone only billed under this code because it knew that otherwise this particular FIP would not pay it for an office visit.

On August 28, 2011, Defendant Fowler allegedly saw patient CMB and billed for CPT Code 99213 (code audiologists are not allowed to bill) for an office visit that he did not document that he completed a comprehensive patient history as required.

On May 30, 2013, Defendant Fowler saw patient RAB for CPT 99212 (code audiologists are not allowed to use) for a comprehensive office visit that he did not complete yet he billed FIP $55.00 and was paid .94 with a patient co-pay of $40.00. There was none of the required documentation in the patient's chart to make it eligible to be billed.

On June 29, 2012, Patient EA was seen by Relator. Defendant Keystone fraudulently billed the FIP Code V5010 assessment for hearing aid at $90.00 even though this was an incomplete test due to the fact that Relator did not conduct the MCL or UCL or loudness gross functions. She failed to do so because Defendant Fowler directed her to not conduct that part of the test and the form he would give Relator to complete did not have a space indicated for that part of the test. Defendant Keystone billed this code depending on what the FIP would reimburse.

On June 29, 2012, Patient WA was seen by Relator unsupervised. Defendant Keystone billed FIP V5010 assessment for hearing aid at $90.00 even though this was never a completed test for failure to conduct the MCL or UCL or loudness

gross functions because Defendant Fowler directed Relator not to conduct that part of the test and the form he would give Relator to complete did not have a space indicated for the part of the test.

On June 25, 2013, Relator saw patient TB for only a hearing aid assessment (V5010) however Defendant Keystone billed FIP for CPT 92557 a comprehensive audiological test at $97.00 with payment of $36.16, CPT 99201 office visit (a code not allowed to be billed by an audiologist and wasn't conducted by Relator) at $65.00 and paid $11.78, plus Defendant Keystone also billed the patient TB a $30.00 copay for that service that wasn't done. Defendant Keystone also billed V5261 a binaural BTE hearing aids at $4,200.00 and was paid $1,000.00. Defendant Keystone billed all the above services / products under Defendant Fowler's NPI number because Relator was not a registered / credential provider.

Relator questioned Defendant Fowler about not completing the requirements of the test and he said "it was not required."

49 Pa. Code § 45.102 (2)(c) *Principle of Ethics I.*

> (1) Because speech-language pathologists, audiologists and teachers of the hearing-impaired provide nonmedical and nonsurgical services, medical diagnosis and medical treatment by these persons are specifically to be considered unethical and illegal. (ii) A licensee who performs examinations and treatments shall use evaluation instruments, techniques and procedures commonly recognized by their profession and compatible with their education, expertise and professional competence.

Relator identified a long-standing practice of improper coding and billing FIP for office visits. The issues that the Relator identified included: (1) billing for E/M services (office visits) at levels that were not supported by the documentation in the medical record; and (2) billing for E/M services that were included within the reimbursement for the administration of services and thus were not separately billable.

Defendant Keystone would bill for a certain code if it knew if that particular FIP would pay for that service without questions. Often there would be no documentation in the chart as to show why certain tests were done.

The False Claims Act, 31 U.S.C. § 3729 addresses filing claims for incomplete procedures. A common example for audiologists is filing a claim for CPT code 92557, comprehensive audiometry, which includes bilateral testing of pure tone air and bone conduction, speech reception thresholds, word recognition testing. If bone conduction is not performed and (92557) is filed, this is a False Claim. In this example, air conduction (92552), speech reception thresholds (92555) and word recognition testing (92556) should be filed.

Defendant Keystone by and through Defendants Fowler and/or Price billed for Code '92579' a visual reinforcement audiometry ("VRA") at the incorrect code of '92557' which certifies that the audiologist performed an air and bone conduction measurement, speech thresholds, and speech discrimination; the pure-

tone information may have been obtained using play techniques. Defendant Keystone by and through Defendants Fowler and/or Price would not actually conduct the speech awareness threshold.

Upon information and belief, Defendant Price also failed to actually perform a comprehensive office exam and knew or should have known that Defendant Keystone was billing the FIP as if she had completed this exam.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that they knew were ineligible for reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants

Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

4. Billing For Services Not Medically Necessary

Both State and Federal Healthcare Programs determine reimbursements to providers based on the medical necessity of procedures and services. Medical necessity must be determined prior to the performance of each medical service and must be clearly documented in a referring physician's order. *It cannot be determined retroactively.*

Federal Regulations define a "prior determination of medical necessity" to mean "an individual decision by a Medicare contractor, before a physician's service is furnished, as to whether or not the physician's service is covered" by the federal healthcare program. 42 C.F.R. § 410.20.

Federal Insurance Programs will only pay for services considered "reasonable and necessary" which includes audiology diagnostic services. If the service is not medically necessary, FIP will not reimburse the provider.

Pursuant to the CMS Manual System, Pub 100-02 Medicare Benefit Policy, Transmittal 84, Change Request 5717, dated February 28, 2009, "audiological tests

may be ordered for a Medicare beneficiary when the reason for the test is not for the purpose of fitting or modifying a hearing aid."

The payment for audiological diagnostic tests is determined by the reason the tests were performed, rather than by the diagnosis or the patient's condition.

Payment by FIP for an audiological diagnostic test is not allowed when (1) The type and severity of the current hearing, tinnitus or balance status needed to determine the appropriate medical or surgical treatment is known to the physician before the test; or (2) The test was ordered for the specific purpose of fitting or modifying a hearing aid.

Payment of audiological diagnostic tests is allowed for other reasons and is not limited, for example, by: Any information resulting from the test including, for example: Confirmation of a prior diagnosis; Post-evaluation diagnoses; or Treatment provided after diagnosis, including hearing aids, or The type of evaluation or treatment the physician anticipates before the diagnostic test.

a. SCHEDULED YEARLY EXAMS / SENT REMINDERS

The use of reminder cards to solicit a patient for annual or routine hearing testing could be construed as a solicitation of a Medicare referral. Moreover, billing FIP for annual or routine hearing tests even with a physician order but without true medical necessity is inappropriate and fraudulent, according to CMS.

Re-evaluation is appropriate at a schedule dictated by the ordering primary physician when the information provided by the diagnostic test is required, for example, to determine changes in hearing, to evaluate the appropriate medical or surgical treatment or evaluate the results of treatment. For example, re-evaluation may be appropriate, even when the evaluation was recent, in cases where the hearing loss, balance or tinnitus may be progressive or fluctuating, the patient or caregiver complains of new symptoms, or treatment (such as medication or surgery) may have changed the patient's audiological condition with or without awareness by the patient.

Medicare FIP allows for coverage of medically reasonable and necessary testing initiated by the ordering family doctor. Billing FIP for annual or routine hearing tests with a physician order but without true medical necessity is inappropriate and fraudulent.

The use of reminder cards to solicit a patient for annual or routine hearing testing could be construed as a solicitation of a Medicare referral. The Medicare Anti-Kickback Statute could be applied in instances where you attempt to solicit a Medicare order for Medicare reimbursed services. The initiation of the hearing test through the use of a reminder card could be considered a solicitation. Violations of the Anti-Kickback Statute Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)), previously codified at sections 1877 and 1909 of the Act, provides

criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Medicare or State health care programs. The offense is classified as a felony, and is punishable by fines of up to $25,000 and imprisonment for up to 5 years.

Defendant Keystone by and through Defendant Fowler would treat "Skills" patients, who came from group homes and would be mentally retarded or disabled. Defendant Keystone would bill the FIP for the testing of these patients when it was not noted to be medically necessary and would be billed office visits, when it was not warranted because no patient history was taken, and there were hardly ever any notes in the charts. For many of the patients, Defendant Fowler would indicate on their charts that they were to be tested "yearly", even though he is not allowed to refer them back to himself on a yearly basis.

An audiologist may not treat a patient in a nursing home when he knows that the patient is not likely to have significant communication benefit from speech or language therapy even if the person may be reimbursed by Medicare; it is unknown at this time if Defendant Fowler and/or Defendant Price documented the medical necessity of the nursing home patients they serviced.

Defendant Keystone would send reminder cards to patients to schedule their yearly appointments and or recruit patients through some advertising, including but

not limited to the following patients: BIC - 01/25/12, Defendant Fowler recommended she be tested; ARC - 04/15/14, Defendant Fowler told her to get new aids before she turns twenty-one (21), so insurance will pay; GAD - 01/17/13, 01/24/14 (two separate claims for yearly exam); MD - 01/12/12, 01/17/13, 01/24/14 (three separate claims); MMD - 10/16/13, came in from Defendant Keystone advertisement mailing; BLH - 06/11/14; JMR - 11/29/11, received Defendant Keystone letter about demo; RJR -11/22/11, received mailing from Defendant Keystone; and PDS - 04/14/11, came in from Defendant Keystone newspaper ad.

Upon information and belief, Defendant Price knew that some of the patients she treated made the appointments only because they received a yearly reminder and/or mailing, which makes that patient's treatment ineligible for payment from FIP and knew Defendant Keystone still billed the FIP for these visits.

Defendants Keystone, Fowler and Price did act and/or conspired to intentionally and knowingly fail to meet the FIP conditions of participation and knowingly falsified or failed to supervise the falsification of the certification that they had met the conditions of participation (including each claim submitted), by knowingly submitting and causing the submission and/or failing to supervise the submission of false and fraudulent claims, Defendants Keystone, Fowler, and Price therefore caused the submission of claims that were false and not eligible for reimbursement to FIP. By causing these claims that they knew were ineligible for

reimbursement to be submitted to and paid for by FIP, Defendants Keystone, Fowler and Price also made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. Had FIP known that these claims were only approved for coverage as a result of such false and fraudulent statements, they would not have reimbursed for those claims. Defendant Keystone accepted payment for each false claim made with these faulty conditions, paid Defendants Fowler and Price, and it failed to reimburse the FIP for these illegal / ineligible payments. Because FIP paid reimbursements for the resulting false claims, the FIP incurred and continues to incur significant and material damages due to Defendants' fraudulent actions. Upon information and belief said Defendants' fraudulent actions are continuing.

b. FAILURE TO SECURE REFERRALS OR CLEARANCES

28 Pa Code § 25.212 provides: (a) Whenever a medical examination is performed under the Act or Federal Requirements, before fitting and selling a hearing aid the registrant shall ensure that a medical recommendation has been signed by the examining physician, within 180 days *before the sale*, on a form which includes the following statement or its equivalent:

I have medically evaluated the hearing ability of
_____
(Patient's Name)
and a hearing aid may be beneficial to this person.
_____
(Signature of Physician)

Medicare pays for audiological diagnostic tests under the benefit of "other diagnostic tests." The test may be order by a primary physician for any beneficiary when there is suspicion of impairment of the auditory systems. *CMS Manual System Pub.* 100-02 Medicare Benefit Policy #5717 (2008).

To be reimbursable, audiology medical services for eligible patients ordinarily must be furnished by a physician (family doctor) or, if by a non-physician, "under [an] appropriate level of supervision by a physician." 42 C.F.R. § 410.32. One limitation is that the physician 'family doctor' must order the service; diagnostic audiology services performed by an audiologist without a primary physician order are not covered. *Medicare Benefit Policy Manual, Pub. 100-02 at ch. 15 § 80.3(B).*

Medicare does, however, cover diagnostic audiology services "personally furnished by a qualified audiologist" even without primary physician supervision—albeit with some limitations. *Centers for Medicare & Medicaid Services, Medicare Benefit Policy Manual*, Pub. 100-02, at ch. 15, § 80.3(A); see Doc. 102 at ¶ 29; 42 C.F.R. § 410.32(b)(2)(ii). One limitation is that a primary care physician must order the service; diagnostic audiology services "performed by an audiologist without a physician order … are not covered." *Medicare Benefit Policy Manual*, supra, at ch. 15, § 80.3(B).

An audiologist may request a referral from a primary physician on behalf of the patient only if this request is *before* the audiologist treats the patient.

49 Pa. Code § 45.102 (d)(2) *Ethical Proscriptions are as follows*: (i) A licensee may not exploit a person in the delivery or payment for professional services, as provided for under the Act. Exploitation of services includes accepting persons for treatment or by continuing treatment when benefits cannot reasonably be expected.

49 Pa. Code § 45.102(e) *Principle of Ethics III* provides (1) A licensee shall maintain high standards of professional competence, (iii) A licensee shall identify competent, dependable referral sources for a person served.